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# **EXHIBIT 4**

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC. )  
Plaintiff, )  
v. ) Civil Action No. 01-1997  
TYCO HEALTHCARE GROUP LP, )  
et al., )  
Defendants. )

MEMORANDUM

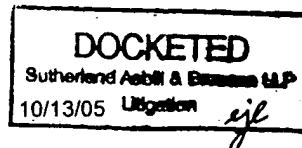
Gary L. Lancaster,  
District Judge.

October 12, 2005

This is an action in patent infringement. Plaintiff, Medrad, Inc., alleges that defendants, Tyco Healthcare Group LP, Mallinckrodt Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd., have infringed on its patent in violation of the Patent Act, 35 U.S.C. §271, et seq. The patent asserted in this case, United States Patent No. RE 37,602 (the '602 Patent), discloses and claims inventions relating to patient infusion systems for use with Magnetic Resonance Imaging, or MRI, systems. Plaintiff seeks injunctive and monetary relief.

Before the court are the parties' cross motions for summary judgment regarding the validity of plaintiff's reissued patent. Defendants filed a motion for summary judgment of invalidity of the '602 Patent based on defective reissue [doc. no. 211]. Defendants argue that under the reissue statute, 35 U.S.C. §251, a patentee may secure reissue of a patent only to correct one of

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four statutorily identified errors: a defect in the specification, a defect in the drawings, or an error in either claiming too much or too little in the patent. According to defendants, because plaintiff did not file the reissue application that resulted in the '602 Patent to fix one of these four errors, the '602 Patent is invalid.

Plaintiff also filed a motion for summary judgment of no invalidity based on its filing of the reissue application [doc. no. 216]. Plaintiff argues that a reissue application can be filed to correct any number of mistakes made during the prosecution of a patent. Plaintiff contends that the United States Patent and Trademark Office (the PTO) properly issued the '602 Patent to correct an error caused by a failure to file the appropriate declarations during prosecution of a predecessor patent.

For the reasons set forth below, defendants' motion will be granted and plaintiff's motion will be denied. Because the patent sued upon in this case has been deemed invalid as a result of these rulings, this case will be closed.

I. BACKGROUND

The facts material to this issue are not in dispute.

There were two predecessor patents to the '602 Patent, both of which plaintiff owned by assignment. First, U.S. Patent No. 5,494,036 (the '036 Patent), issued on February 27, 1996. And second, U.S. Patent No. RE 36,648 (the '648 Patent), issued on April 11, 2000. Plaintiff sought to reissue the '036 Patent to broaden its claims, and filed a reissue declaration regarding that desired change. During prosecution of the application, however, the PTO actually narrowed plaintiff's claims.<sup>1</sup> In addition, during the prosecution, plaintiff added two more inventors to the patent.

Therefore, while plaintiff originally sought reissue to correct a purported underclaiming error, and filed a reissue declaration regarding that error, the PTO reissued the patent to correct an overclaiming error and an inventorship error. For reasons not clear from the record, plaintiff failed to file a supplemental reissue declaration regarding the two errors

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<sup>1</sup> Because reissue is essentially a reprocsecution of all claims, original claims that a patentee wants to maintain unchanged may nevertheless be rejected on any statutory ground, or otherwise altered. Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1563 (Fed. Cir. 1989) (citing authorities).

identified and ultimately corrected by the PTO, as it was required to do under PTO Rules. 37 C.F.R. §1.175.

Shortly after the PTO issued the '648 Patent, plaintiff filed a complaint with the U.S. International Trade Commission alleging illegal importation of infringing devices in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. §1337. The Administrative Law Judge found, via summary determination, that the '648 Patent was invalid because plaintiff failed to file supplemental reissue declarations regarding the overclaiming and inventorship errors that were ultimately corrected by the PTO. The ALJ's initial determination became the final determination of the Commission, and the ITC investigation was terminated on February 12, 2001.

Before the ALJ's initial determination became final, plaintiff filed an application with the PTO seeking reissue of the '648 Patent, which itself was a reissued patent. Plaintiff filed this second reissue application in order to remedy the problems with the '648 Patent that were identified by the ALJ, namely, the lack of supplemental reissue declarations regarding the overclaiming and inventorship errors that were ultimately corrected by the '648 Patent. On March 26, 2002, the PTO issued the '602 Patent, which is the basis of plaintiff's complaint in this case. The '602 Patent does not change the specification,

drawings, claims, or any other part of the '648 Patent. The only difference between the two patents is that during the prosecution of the '602 Patent the missing supplemental reissue declarations, identified as lacking by the ITC, were allegedly filed.<sup>2</sup>

II. STANDARD OF REVIEW

Fed.R.Civ.P. 56(c) provides that summary judgment may be granted if, drawing all inferences in favor of the non-moving party, "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." To defeat summary judgment, the non-moving party cannot rest on the pleadings, but rather must go beyond the pleadings and present "specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

The mere existence of some factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. A dispute over those facts that might affect the outcome of the suit under the governing substantive

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<sup>2</sup> Defendants dispute whether the declarations that were filed during the prosecution of the '602 Patent actually satisfy the requirements of PTO Rule 1.175. We need not reach that issue, however, given our disposition of these motions.

law, i.e. the material facts, however, will preclude the entry of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Similarly, summary judgment is improper so long as the dispute over the material facts is genuine. Id. In determining whether the dispute is genuine, the court's function is not to weigh the evidence or to determine the truth of the matter, but only to determine whether the evidence of record is such that a reasonable jury could return a verdict for the non-moving party. Id. at 248-49. Under these standards, the non-moving party must do more than show there is "some metaphysical doubt" as to the material facts. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

"Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" Matsushita Elec., 475 U.S. at 587 (citations omitted). In summary, the inquiry under a Rule 56 motion is whether the evidence of record presents a genuine dispute over material facts so as to require submission of the matter to a jury or whether the evidence is so one-sided that the movant must prevail as a matter of law because no reasonable jury could return a verdict in her favor.

III. DISCUSSION

The dispositive question presented by these cross motions for summary judgment is whether the reissue statute, 35 U.S.C. §251, can be used to correct a mistake that plaintiff made during the prosecution of the predecessor patent, *i.e.*, failing to file supplemental reissue declarations in compliance with PTO Rule 1.175. Defendants contend that section 251 cannot be used to remedy a procedural mistake made during the prosecution of a predecessor patent. According to defendants, by statute, errors correctable by reissue are limited to those that remedy a defect found in the specification, drawings, or claims of a patent. Defendants argue that because the '602 Patent makes no change to these parts of the predecessor patent the reissued patent is invalid.

Plaintiff, on the other hand, contends that courts routinely allow patent holders to fix a variety of procedural mistakes and errors made during the prosecution of a patent pursuant to section 251. Plaintiff emphasizes that the statute is remedial in nature and should be construed broadly. According to plaintiff, it proceeded appropriately under section 251 in order to fix the failure to file supplemental reissue declarations during the prosecution of the predecessor patent.

Because we find that section 251 requires that some error in the specification, drawings, or claims of the patent be corrected as a result of the reissue process, we grant defendants' motion for summary judgment. Although we recognize that the reissue statute is remedial and must be construed broadly, we cannot interpret a federal statute in a way that eliminates the very phrases of limitation from its text. Were we to adopt plaintiff's reasoning that a patent holder could secure, by reissue, a patent that is the same in all respects on its face, but corrects a mistake made during the prosecution of a predecessor patent that results in the patent being invalid, we would do just that. Neither the statute, nor the cases interpreting it, justify such a result.

While we recognize that this holding produces a harsh result -- ultimately, plaintiff's patent is invalidated because it failed to file a supplemental declaration with the PTO -- we cannot reconcile plaintiff's legal argument with the language of section 251, and the controlling case law interpreting it. Perhaps the language of section 251 will, or should, change. However, it is not the province of this court to do so.

A. Legal Authority

1. Validity of Patent

A patent, including a reissued patent, is presumed to be valid. 35 U.S.C. §282; Westvaco Corp. v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir.<sup>3</sup> 1993); Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359-60 (Fed. Cir. 1984). Therefore, a successful challenge to the validity of a patent, whether regularly issued, or issued pursuant to re-examination or reissue procedures, must meet the clear and convincing evidence standard. Kaufman Co., Inc. v. Lantech, Inc., 807 F.2d 970, 973-74 (Fed. Cir. 1986).

2. The Reissue Statute

Section 251 of the Patent Act provides for reissue of defective patents. 35 U.S.C. §251. The section, in pertinent part, states:

Whenever any patent is, through error without deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the

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<sup>3</sup> The Court of Appeals for the Federal Circuit issues controlling precedent in matters involving patents. 28 U.S.C. §1295(a).

surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent

35 U.S.C. §251 (emphasis added). By its own terms, section 251 requires that the patentee base his application for reissue upon one of four specified grounds statutorily identified as correctable defects. In re Amos, 953 F.2d 613, 616 (Fed. Cir. 1991). This error requirement limits the availability of reissue to certain correctable errors. Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1479 (Fed. Cir. 1998). Again, these correctable errors are: (1) a defect in the specification; (2) a defect in the drawings; (3) an error caused by claiming more than one is entitled to (an overclaiming error); or (4) an error caused by claiming less than one is entitled to (an underclaiming error). As such, a reissued patent must result in a change to the specification, drawings, or claims of the predecessor patent. In re Clement, 131 F.3d 1464, 1472 (Fed. Cir. 1997); In re Rogoff, 261 F.2d 601, 605-06 (C.C.P.A.<sup>4</sup> 1958) (finding that there is no statutory basis for reissue where the "new" claims are of the same scope as the claims in the predecessor patent).

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<sup>4</sup> The Court of Customs and Patent Appeals is the predecessor to the Court of Appeals for the Federal Circuit, and its decisions are binding precedent in the Federal Circuit. See South Corp. v. United States, 690 F.2d 1368, 1369 (Fed. Cir. 1982).

The statute is remedial in nature, is based on fundamental principles of equity and fairness, and should be construed liberally. In re Doyle, 293 F.3d 1355, 1358 (Fed. Cir. 2002) (quoting In re Weiler, 790 F.2d 1576, 1579 (Fed. Cir. 1986)). Notwithstanding its remedial nature, the Court of Appeals for the Federal Circuit has stated that section 251 is not a panacea designed to cure every mistake that might be committed by an applicant or his attorney. Id. (quoting In re Orita, 550 F.2d 1277, 1281 (C.C.P.A. 1977)); see also In re Weiler, 790 F.2d at 1579 (stating that "not every event or circumstance that can be labeled 'error' is correctable by reissue").

B. Legal Analysis

The first hurdle that a reissued patent must overcome is whether "a proper ground for reissue existed under section 251." In re Clark, 522 F.2d 623, 625 (C.C.P.A. 1975). A determination of whether a reissue application has met the statutory requirements of section 251 is a question of law. In re Clement, 131 F.3d at 1468. As detailed above, section 251 provides for reissue of a patent that is deemed invalid due to four specific errors: a defect in the specification, a defect in the drawings, an underclaiming error, or an overclaiming error. 35 U.S.C. §251.

In this case, plaintiff filed a reissue application in order to correct the error in the '648 Patent identified by the ITC, i.e., the lack of supplemental reissue declarations addressed to the overclaiming and inventorship issues ultimately corrected by the PTO. Plaintiff does not contend that this correction fits into one of the four statutorily identified errors. Instead, plaintiff asserts that the Court of Appeals for the Federal Circuit, as well as other courts, have ruled that procedural errors are correctable through reissue, without regard to the identification of a statutorily defined defect. However, the cases on which plaintiff relies do not support that argument.

1. Court of Appeals for the Federal Circuit Cases

The cases from the Court of Appeals for the Federal Circuit that plaintiff relies on do not hold that section 251 can be utilized to correct procedural errors made during the prosecution of a predecessor patent, which may affect the ultimate validity of the patent, but have no effect on the specification, drawings, or claims of the patent itself. Rather, the majority of the cases involve straightforward instances where the reissue statute was used to correct erroneous claims. See In re Doyle, 293 F.3d at 1358; Scripps Clinic & Research Foundations v. Genetech, Inc., 927 F.2d 1565, 1575 (Fed. Cir. 1991); In re Wilder, 736 F.2d

1516, 1518 (Fed. Cir. 1984); Ball Corp. v. United States, 729 F.2d 1429, 1434 (Fed. Cir. 1984).

Even in In re Bennett, 766 F.2d 524 (Fed. Cir. 1985), a case characterized by plaintiff as key to deciding this issue in its favor, the patentee sought reissue in order to change the language of the patent's claims. Bennett, 766 F.2d at 525. The patentee did not file a reissue application in order to correct a "procedural error"; rather, a "procedural error" occurred when the wrong person signed the reissue application. Id. The Court of Appeals for the Federal Circuit approved of the patentee fixing this mistake by filing a supplemental document reflecting the correct signature -- the inventor's. Contrary to plaintiff's contention, the court did not find that the patentee could make that correction by filing a reissue application under section 251.

Instead, the court ruled that section 251 proceedings are not insulated from those provisions of the Patent Act that enable patentees to correct a variety of errors in how documents are signed, and how inventors are listed on documents. In reaching this conclusion, the court pointed out that section 26 of the Patent Act allows for provisional acceptance of defectively executed documents and that sections 116 and 256 provide for amendments to correct errors in inventorship. Id. at 526-28.

Admittedly the court also discussed the remedial nature of section 251 and the principles of equity and fairness behind it. Id. at 528. However, the holding in Bennett was that a patentee could, pursuant to other sections of the Patent Act, correct an error in how a reissue application was executed, and that the correction would "relate back" to the original filing date of the reissue application. Therefore, Bennett is distinguishable from this case, and does not support plaintiff's argument that the Court of Appeals for the Federal Circuit has allowed patentees to use section 251 to fix procedural errors.

We have found no other opinion issued by the Court of Appeals for the Federal Circuit interpreting section 251 in the way plaintiff suggests. Rather, all of the cases addressing this issue identify, as the first step in the analysis, which of the four statutorily identified errors the patentee is seeking to correct under section 251. There are no cases from the Court of Appeals for the Federal Circuit supporting plaintiff's expansive interpretation of section 251.

2. Other Appellate Court Cases

Nor do any of the other cases relied upon by plaintiff support that interpretation. Plaintiff relies heavily on Brenner v. State of Israel, 400 F.2d 789 (D.C. Cir. 1968) and A.F. Stoddard & Co., Ltd. v. Dann, 564 F.2d 556 (D.C. Cir. 1977) to support its argument that section 251 can be used to fix procedural prosecution errors. Although these cases do stretch the bounds of section 251 to, and perhaps beyond, its limits, they do not compel the result that plaintiff seeks in this case.

Firstly, these are decisions of the Court of Appeals for the District of Columbia Circuit, not the Court of Appeals for the Federal Circuit, which issues precedential opinions in the realm of patent cases. Secondly, the cases are factually and legally distinguishable from this case.

(a) Brenner v. State of Israel

In Brenner, the patentee filed a reissue application in order to remedy his failure to file a certified copy of the foreign patent under which he claimed priority during prosecution of the predecessor patent. Brenner, 400 F.2d at 790. The failure to file that patent violated section 119 of the Patent Act, and made the patentee's priority claim ineffective. Id.

The District Court found that the reissue statute was sufficiently broad to entitle the patentee to a reissued patent that included a priority claim based on his foreign patent. Id. at 790. The Court of Appeals for the District of Columbia Circuit affirmed, guided by its obvious belief that the patentee should not lose his priority rights due to a "trivial clerical error." Id. at 791. However, the court also grounded its ruling in the statutory language of section 251 by equating the loss of an effective priority 'claim' with an underclaiming error. Id. (finding that because the error caused the patentee to lose the benefit of his claim of priority, the "patentee claim[ed] ... less than he had a right to claim in the patent").

The instant case does not deal with an attempt to fix a "claim" of priority, and is distinguishable on that ground. In addition, Brenner actually emphasizes the importance of making a threshold finding that the reissue application fits within the language of section 251. For these reasons, Brenner is not particularly helpful to plaintiff's argument that section 251 can be used to fix procedural mistakes that fall outside the scope of the four statutorily defined defects.

(b) A.F. Stoddard & Co. v. Dann

We find Stoddard to carry even less weight due to its lack of any meaningful discussion of section 251, its requirements or limitations, or the cases applying it. In Stoddard, the Court of Appeals for the District of Columbia Circuit permitted a patentee to change the name of the inventor listed on the patent under section 251. Stoddard, 564 F.2d at 558. In so doing, the court overruled the Patent Office Board of Appeals's decision that "section 251, even if most liberally construed, does not authorize the reissuance" of a patent in the name of a different inventor. Id. at 561.

While the Stoddard opinion includes lengthy commentary on the constitutional basis for the patent system, and specifically the role of inventorship in that system, the patent system's requirement of full disclosure, the notion of harmless error, and the inequity of putting form over substance, it remarkably does not include a discussion of whether a proper statutory ground for reissue existed under section 251. The Court of Appeals for the Federal Circuit has instructed that this is the first question that must be answered in determining the validity of a reissued patent. In re Clark, 522 F.2d at 625, In re Wilder, 736 F.2d at 1518. For this reason alone, the Stoddard decision is of questionable value.

In addition, the court's holding was based on an interpretation of another section of the Patent Act, namely section 116, which allows a patent application to be amended to correct a mistake in how joint inventors are listed. 35 U.S.C. §116. The court found that section 116 could be read as sufficiently expansive to justify the inventorship correction requested by the patentee. Stoddard, 564 F.2d at 567. The court did not substantively discuss section 251 in the opinion at all. In fact, when the court did mention the statute in the conclusion of the opinion, it did so only to point out that the patentee could have obtained the same correction under section 256, but chose to proceed under section 251 instead. Id. at 567 & n.16. This opinion cannot be fairly read to hold that a patentee can use section 251 to fix procedural mistakes in a patent. Therefore, Stoddard does little to advance plaintiff's argument.

### 3. Cases Cited in the MPEP

The cases cited in the Manual of Patent Examining Procedure similarly do not support plaintiff's argument that section 251 can be used to correct procedural errors. Instead, each of the examples listed as a "proper ground" for filing a reissue application result in a change to the specification, drawings, or

claims of the patent, which some tribunals have defined to include inventorship or priority "claims" of a patent. See Ex parte Scudder, 169 U.S.P.Q. 814, 815 (B.P.A.I. 1971) (allowing corrections to be made to the named inventor under section 251 because the mistake caused the inventors to "claim" more than, or less than, they had a right to claim); Sampson v. Comm'r. of Patents and Trademarks, 195 U.S.P.Q. 136, 137-38 (D.D.C. 1976) (allowing information to be added to abandoned patent applications in order to perfect a "claim" of priority).

4. Summary

In short, none of the cases plaintiff relies on support the contention that section 251 can be used to fix procedural mistakes. Nor do any of the cases support plaintiff's reading of the statute, which eliminates the "by reason of" limitation entirely and allows any error to be fixed as long as it was inadvertent and results in a patent being invalid. Rather, the courts have consistently interpreted section 251 according to its own terms, which require that the mistake sought to be remedied through reissue be one of the four statutorily identified errors. As such, defendants have satisfied their burden to prove, by clear and convincing evidence, that as a matter of law plaintiff's patent is invalid.

While we recognize that the PTO permitted plaintiff to use the reissue procedure to fix its procedural mistake, the PTO is not always correct in its interpretation and application of the reissue statute. See e.g. In re Hounsfield, 699 F.2d 1320 (Fed. Cir. 1983) (PTO refused reissue due to a lack of intent to claim; Court of Appeals for the Federal Circuit reversed, finding that PTO erroneously viewed lack of intent to claim as precluding reissue); Fontijn v. Okamoto, 518 F.2d 610, 621-23 (C.C.P.A. 1975) (reversing decision of PTO Board of Patent Interferences that perfecting a claim of priority through reissue broadens the claims of a patent).

Although this may produce a harsh result, especially considering that plaintiff filed the second reissue application to remedy a mistake that was apparently acquiesced to by the PTO during the prosecution of the first reissue, it is the result mandated by the statute, as it is currently drafted, and the controlling case law.

IV. CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment is granted, and plaintiff's motion for summary judgment is denied. An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC. )  
Plaintiff, )  
 )  
v. ) Civil Action No. 01-1997  
 )  
TYCO HEALTHCARE GROUP LP, )  
et al., )  
Defendants. )

ORDER

Therefore, this 12<sup>th</sup> day of October, 2005, IT IS HEREBY ORDERED that defendants' motion for summary judgment [doc. no. 211] is GRANTED;

IT IS FURTHER ORDERED that plaintiff's motion for summary judgment [doc. no. 216] is DENIED;

IT IS FURTHER ORDERED that all other pending motions are deemed moot, and;

IT IS FURTHER ORDERED that final judgment in this Court is entered pursuant to Rule 58 of the Federal Rules of Civil Procedure and the Clerk of Court is directed to mark this case closed.

BY THE COURT:



cc: All Counsel of Record

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